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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/991,573	11/20/2001	Paul H. Burmeister	1001.1145105	4239

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EXAMINER

SZMAL, BRIAN SCOTT

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 04/17/2003

4

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/991,573

Applicant(s)

BURMEISTER ET AL. *CM*

Examiner

Brian Szmaj

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3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 28-35 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 28-35 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 28-32 are rejected under 35 U.S.C. 102(b) as being anticipated by De Toledo (WO 91/00051 A1).

De Toledo discloses a steerable highly elongated guidewire and further discloses an elongated core having a proximal region and a distal region, the distal region having a proximal portion and a distal portion; a radiopaque coil disposed about the distal portion of the core; a plastic jacket disposed about the proximal portion of the core and the radiopaque coil; the jacket is in intimate contact with the coil; the plastic jacket is in intimate contact with the proximal portion of the core; the plastic jacket has a smooth outer surface; and the radiopaque coil is connected to the distal end of the core to form a connection, and wherein the plastic jacket encapsulates the connection. See Abstract; and Page 6, lines 3-19.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 33 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over De Toledo (WO 91/00051 A1) as applied to claim 32 above, and further in view of Hammerslag et al.

De Toledo, as discussed above, discloses a guidewire with a radiopaque coil and a plastic sleeve, but fails to disclose the distal portion of the core having a relatively flat cross-sectional shape; and the proximal portion of the core has a relatively round cross-sectional shape.

Hammerslag et al disclose a steerable medical device and further disclose the distal portion of the core having a relatively flat cross-sectional shape; and the proximal portion of the core has a relatively round cross-sectional shape. See Figures 24A, 24B, 26 and 27.

Since both De Toledo and Hammerslag et al disclose steerable guidewires, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of De Toledo to include a flat cross-section at the distal portion of the core as well as a round cross-section at the proximal portion of the core, as per the teachings of Hammerslag et al, since it is well known in the art to utilize different shapes of the core wire at the distal section of the guidewire to influence the flexibility of the distal section of the wire.

5. Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over De Toledo (WO 91/00051 A1) in view of Hammerslag et al.

De Toledo, as discussed above, discloses a guidewire with a radiopaque coil and a plastic sleeve in contact with the core and coil (See Abstract; and Page 6, lines 3-19),

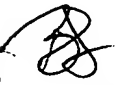
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but fails to disclose the distal portion of the core having a relatively flat cross-sectional shape; and the proximal portion of the core has a relatively round cross-sectional shape.

Hammerslag et al, as discussed above, disclose a steerable guidewire and further disclose the distal portion of the core having a relatively flat cross-sectional shape; and the proximal portion of the core has a relatively round cross-sectional shape. See Figures 24A, 24B, 26 and 27.

Since both De Toledo and Hammerslag et al disclose steerable guidewires, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of De Toledo to include a flat cross-section at the distal portion of the core as well as a round cross-section at the proximal portion of the core, as per the teachings of Hammerslag et al, since it is well known in the art to utilize different shapes of the core wire at the distal section of the guidewire to influence the flexibility of the distal section of the wire.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Szmaj who's telephone number is (703) 308-3737 and group fax number is (703) 308-0758. The examiner can normally be reached on Monday-Friday, with second Fridays off.


BS
April 11, 2003


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